## REMARKS/ARGUMENTS

Claims 1-52 are pending in the application. Claims 8-12, 14-20, and 23-49 are withdrawn. Claims 1-2, 4-5, 7, and 47 have been amended, and new claims 50-52 have been added. Support for the amendments and new claims can be found throughout the specification, particularly pages 45-46. No new matter has been added. Reexamination and reconsideration in view of the amendments and following remarks are respectfully requested.

The Restriction Requirement

The Examiner has acknowledged that claim 1 is a linking claim and that claims 1-7, 13, 21, and 22 will be examined. Clarification is requested as to the remainder of the claims in groups II – XVIII. Applicants submit that upon notice of allowance of the broad claim, the claims of groups I – XVIII should be rejoined. As stated in MPEP 809.03, a linking claim is identified when "an application has claims to two or more properly divisible inventions, so that a requirement to restrict the application to one would be proper, but presented in the same case are one or more claims (generally called "linking" claims) inseparable there from and thus linking together the invention otherwise divisible". Under linking claim practice, upon allowance of the linking claim, the restriction requirement as to the linked inventions is withdrawn and any claims depending from or otherwise including all of the limitations of the allowable linking claims will be entitled to examination in the instant application.

The claims in Groups I-XVIII are clearly linked by original broad claim 1 that recites a pharmaceutical composition comprising an "activin antagonist." Therefore, the Examiner should proceed with examination under linking claim practice as outlined in MPEP 809.03.

The Examiner is asked to clarify on the record what claims will be rejoined and examined at such time that the linking claim is found allowable.

Applicants further reserve the right to petition the rejoinder of Groups I-XVIII and XIX.

The Objection to the Specification Should Be Withdrawn

The specification was objected to for failure to comply with 37 C.F.R. §§ 1.821 through 1.825 because the specification describes and the claims are drawn to proteins identified by accession number only. A sequence listing has been compiled for each of the sequences described in NCBI Accession Nos. XP_003891 and AAH04107 (SEQ ID NO:1), NP_005851 (SEQ ID NO:2), M13436 (SEQ ID NO:3, nucleotide sequence; and SEQ ID NO:4, amino acid sequence), and M13437 (SEQ ID NO:5, nucleotide sequence; and SEQ ID NO:6, amino acid sequence). Applicants note that the amino acid sequences described in NCBI Accession Nos. XP_003891 and AAH04107 are identical and are thus described by a single sequence identification number. Furthermore, NCBI Accession Nos. M13436 and M13437 each describe a nucleotide sequence and its encoded amino acid sequence, therefore, each of these accession numbers is represented in the sequence listing with a nucleotide sequence and an amino acid sequence. As the requirements under 37 C.F.R. §§ 1.821 through 1.825 have been met by the sequence listing provided herewith, the Examiner is respectfully requested to withdraw the objection to the specification.

The Objection to the Claims Should Be Withdrawn

Claim 5 was objected to because the claimed Markush group recited the word "and" twice. Claim 5 has been amended to delete the first occurrence of the word "and." Accordingly, the objection should be withdrawn.

The Rejections of the Claims based on Double Patenting Should be Withdrawn

Claims 1-7, 13, 21, and 22 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of US Patent No. 5,470,826 (the '826 patent). This rejection should be withdrawn.

The Examiner is reminded that the '826 patent issued November 28, 1995 and thus the rejection of the claims based on obviousness-type double patenting is improper.

The '826 patent is drawn to polypeptides exhibiting an inhibitory action over follitropin. The patent provides no information on formulating or for dosage amounts for the use of the

polypeptides. Accordingly, the patent does not anticipate nor render obvious the currently pending claims.

Claims 1-7, 13, 21, and 22 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 87 of copending Application No. 10/318,283 (the '283 application). This rejection is respectfully traversed.

Claims 1-7, 13, 21, and 22 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 60 of copending Application No. 10/515,049 (the '049 application). This rejection is respectfully traversed.

Claims 1-7, 13, 21, and 22 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 51 and 57-60 of copending Application No. 10/571,837 (the '837 application). This rejection is respectfully traversed.

The immediately referenced nonstatutory obviousness-type double patenting rejections are improper. The present application and the '283, '049, and '837 applications are not commonly owned. Thus, the rejections are improper for the following reasons.

*The Purposes for a Double Patenting Rejection to Prevent the Unjustified Timewise Extension of the Right to Exclude Granted by a Patent and to Prevent Harassment by Multiple Parties Do Not Apply to the Present Case*

Applicants respectfully submit that the present double patenting rejections are improper. MPEP Section 804 indicates that:

> The doctrine of double patenting seeks to prevent the unjustified extension of patent exclusivity of the term of the patent. The public policy behind this doctrine is that:
>
> > The public should . . . be able to act on the assumption that upon the expiration of the patent it will be free to use not only the invention claimed in the patent, but also modifications or variants which would have been obvious to those of ordinary skill in the art at the time the invention was made, taking into account the skill in the art and prior art other than the invention claimed in the issued patent.

MPEP (Rev. 5, Aug. 2006), Section 804, page 800-11.

As further noted in the discussion that follows, "double patenting exists when the right to exclude granted by a first patent is unjustly extended by the grant of a later issued patent or patents. *In re Van Ornum,* 686 F.2d 937, 214 USPQ 761 (CCPA 1982)." Clearly, in the present case, the extension of patent term is not an issue. The present application has a filing date of January 12, 2004 and if issued into a patent would expire before the expiration date of a patent issuing from the '283, '049, and '837 applications.

The prohibition against the unjust extension of patent term is further reiterated in Section 804 of the MPEP, page 800-21, which sets forth that a nonstatutory double patenting rejection "is based on a judicially created doctrine grounded in public policy so as to prevent the unjustified or improper timewise extension of the right to exclude granted by a patent. *In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re White*, 405 F.2d 904, 160 USPQ 417 (CCPA 1969); *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968); *In re Sarett*, 327 F.2d 1005, 140 USPQ 474 (CCPA 1964).

The present application has a filing date that is earlier than the filing dates the '283, '049, and '837 applications. Accordingly there is no unjust patent term extension.

A further rationale for requiring a terminal disclaimer is the concern of possible harassment by multiple assignees. The United States Court of Custom and Appeals in *In re Van Ornum* confirmed that this was a further rationale for requiring a terminal disclaimer and the tying together of the ownership (non-alienation) of two patents (686 F.2d 937, 948, 214 U.S.P.Q 761, 770 (CCPA 1982).

Whenever the courts have discussed the concern of harassment by multiple assignees it has always been in terms of commonly owned patents that might subsequently be assigned or transferred to different parties. The court addressed this common ownership in *In re Van Ornum,* where it stated that "[t]his provision would prevent harassment of an alleged infringer by multiple parties due to **subsequent** different ownership of multiple patents granted as the result

of filing a terminal disclaimer to overcome a double patenting rejection" (686 F.2d at 945, 214 U.S.P.Q at 768; emphasis added). In *Chisom,* a discussion of the issue of harassment by multiple assignees states that "[e]ven though both patents are issued to the same patentee or assignee, it is possible that ownership of the two would be divided by later transfer and assignments" (Chapter 9, section 9.04[2][b][ii]; emphasis added). Since a terminal disclaimer can only be filed where the patents or applications are commonly owned, the requirement that a terminal disclaimer include a non-alienation clause dictates that there is common ownership.

With regard to the '283, '049, and '837 applications and the application at issue, these inventions were never commonly owned and the inventors in each case were by law required to assign to different owners (employers). At no time were these two inventions commonly owned. Accordingly, appellants respectfully submit that the issue of harassment by multiple assignees does not apply to this case.

*There Is No Double Patenting Issue for the Present Application in View of the '283, '049, and '837 applications*

The section of the MPEP that governs the present situation is MPEP 804.03 IV, pages 800-37 through 800-39, regarding rejections under 35 USC 102 and 103 and double patenting. Form paragraph *7.21.01 Provisional Rejection, 35 USC 103(a), Common Assignee or at Least One Common Inventor* should be applied to the present situation. The present application and the '283, '049, and '837 applications do not have a common assignee or are not subject to a joint research agreement as defined by The CREATE Act. The present application and the '283, '049, and '837 applications do share a common inventor.

MPEP form paragraph 7.21.01 indicates that in the present case the claims of the '283, '049, and '837 applications should be provisionally rejected under 35 USC 103(a) as obvious over the present application, which is copending. As stated in the form paragraph, "[b]ased upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e) if published or patented. This provisional rejection under 35 U.S.C.

103(a) is based upon a presumption of future publication or patenting of the conflicting application." MPEP, page 800-38.

As noted in the discussion that follows, this form paragraph should be used by an examiner to provisionally reject claims not patentably distinct from the disclosure in a copending application having an earlier U.S. filing date and also having either a common assignee or at least one common inventor. As noted on page 800-39, "if an application has a later effective U.S. filing date than a conflicting issued patent, the examiner should consider making a rejection in the application, based on the patent, under 35 U.S.C. 102(e) or 102(e)/103(a) using form paragraph 7.15.02 or 7.21.02. The discussion distinguishes the present situation from the situation where the application and the patent are subject to a joint research agreement under The CREATE Act.

The fact overlooked by the Examiner in the present application is the fact that the **present application has an effective filing date that is earlier** than the filing date of the '283, '049, and '837 applications. Thus, the '283, '049, and '837 applications are not prior art for purposes of double patenting under 35 U.S.C. 102 or 103. The present application is the earlier filed application.

In conclusion, based upon the procedures set forth in the MPEP based upon current patent law there is no double patenting issue for the present application in view of the '283, '049, and '837 applications. Accordingly, the double patenting rejections should be withdrawn.

The CREATE Act Safe-Harbor Provisions Do Not Apply to the Present Application

As noted above, the present application and the '283, '049, and '837 applications are not commonly assigned, nor subject to a joint research agreement, as provided by The CREATE Act. Thus, the double patenting concerns brought about by the CREATE Act are not an issue in the present application. The CREATE Act provides a simple means of extending the "safe harbor" provisions of current law that treats inventions of a common owner similarly to inventions made by a single person. To promote collaborative research within organizations, Congress enacted the Patent Law Amendments of 1984, which, inter alia, exempt "common owner" inventors from the application of certain types of prior art and information in obviousness determinations,

subject to the exercise of the same double patenting principles that apply when inventions are made by a single inventor. Importantly, "[p]atents issued under this Act shall be enforceable in the same manner, to the same extent, and for the same term as when patents are issued to a common owner or are subject to common assignment. The doctrine of "obviousness-type double patenting," a judicial doctrine used by courts to prevent patentees from obtaining an unjustifiable extension of the amount of time to exercise a patent's right to exclude, shall apply to such patent." H.R. REP. 108-425, page 5.

As set forth in Department of Commerce RIN 0651-AB76:

> Once an examiner has established a *prima facie* case of obviousness under 35 U.S.C. 103(a), the burden is on the applicant to overcome the rejection by invoking 35 U.S.C. 103(c) as amended by the CREATE Act. . . To overcome such a rejection via the CREATE Act, the applicant must provide a statement in compliance with §1.104(c)(4) to the effect that the prior art and the claimed invention were made by or on the behalf of parties to a joint research agreement, within the meaning of 35 U.S.C. 103(c)(3), which was in effect on or before the date the claimed invention was made, and that the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement. . . . If the applicant disqualifies the subject matter relied upon by the examiner in accordance with the CREATE Act and the procedures set forth in this final rule, the examiner will treat the application under examination and the 35 U.S.C. 102(e), (f), or (g) prior art as if they are commonly owned for purposes of 35 U.S.C. 103.

Federal Register Vol. 70, No. 177, 54259, 54261.

Thus, parties who seek to benefit from the CREATE Act waive the right to enforce any patent separately from any earlier patent that would otherwise have formed the basis for an obviousness-type double patenting rejection. A double patenting rejection is authorized where an applicant invokes the new provisions of 35 U.S.C. 103(c), even though there is neither a common inventor nor a common patent owner. Rule 1.109(b).

As discussed in the MPEP and in the CREATE Act, double patenting rejections may arise as a result of the amendment to 35 U.S.C. 103(c) by the CREATE Act (Pub. L. 108-453, 118 Stat. 3596 (2004)). Congress recognized that this amendment to 35 U.S.C. 103(c) would result in situations in which there would be double patenting rejections between applications not

owned by the same party (see, H.R. Rep No. 108-425, at 5,6 (2003). For purposes of double patenting analysis, the application or patent and the subject matter disqualified under 35 U.S.C. 103(c) as amended by the CREATE Act will be treated as if commonly owned.

> Congress recognized that this amendment to 35 U.S.C. 103(c) would result in situations in which there would be double patenting between applications not owned by the same party. *See* H.R. Rep. No. 108-425, at 5-6 (2003). Therefore, the Office is providing the following guidelines for double patenting rejections based upon a patent or application that is not commonly owned but was disqualified under 35 U.S.C. 103(c) as resulting from activities undertaken within the scope of a joint research agreement, which will be incorporated into the next revision of the MPEP.

Federal Register Vol. 70, No. 177, 54259, 54261.

However, this new category of double patenting created by the CREATE Act does not apply to the present application. Applicants are not seeking to benefit from the provisions provided by the CREATE Act. Furthermore, Applicants cannot take advantage of the provisions of the CREATE Act since there was no joint research agreement in place between the assignee of the present application and the assignee of the '283, '049, and '837 applications. Accordingly, double-patenting under the CREATE Act does not apply to the present application and the rejection should be withdrawn.

Applicants further note that the MPEP section addressing the requirements of a double patenting rejection states that an "[o]bviousness-type double patenting requires rejection of an application claim when the claimed subject matter is not patentably distinct from the subject matter claimed in a ***commonly owned patent***, or a ***non-commonly owned patent but subject to a joint research agreement*** as set forth in 35 U.S.C. 103(c)(2) and (3), when the issuance of a second patent would provide ***unjustified extension of the term*** of the right to exclude granted by a patent." MPEP § 804(II)(B)(1) (citing *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 58 USPQ2d 1869 (Fed. Cir. 2001) and *Ex parte Davis*, 56 USPQ2d 1434, 1435-36 (Bd. Pat. App. & Inter. 2000)) (emphasis added). The present application and the '283, '049, and '837 applications are not commonly owned, nor are they subject to a joint research agreement. Further, there is no unjustified extension of term in this case. Thus, the fundamental purpose for

which the judicially created doctrine of obviousness-type double patenting was intended, i.e., to prevent the unjustified extension of the term of the right to exclude granted by a patent (which purpose is repeated throughout the MPEP), is not present in this case (*See,* MPEP § 804, § 804 (II), § 804(II)(B) and § 804(II)(B)(1)).

Additionally, the MPEP states:

> If the provisions of 35 U.S.C. 103(c)(1) apply to the commonly owned conflicting inventions of different inventive entities or if the provisions of 35 U.S.C. 103(c)(2) apply to non-commonly owned inventions subject to a joint research agreement and thereby obviate the obviousness rejection(s), double patenting rejection(s) should be made (or maintained) as appropriate. **If, however, it is determined that the provisions of 35 U.S.C. 103(c) do NOT apply** because the inventions were not commonly owned or subject to an obligation of assignment to the same person at the time the later invention was made, or because the claimed invention did NOT result from activities undertaken within the scope of a joint research agreement as required by 35 U.S.C. 103(c)(2) and (3), **and** there is evidence of record to indicate that a patent or application is prior art against the application being examined, the examiner should make (A) any appropriate double patenting rejection(s), and (B) the appropriate prior art rejection(s) under 35 U.S.C. 102 and/or 35 U.S.C. 103 in the application being examined.

MPEP § 804.03(IV) (emphasis added). Again, none of these fact patterns identified as appropriate for a double patenting rejection are found in the instant case. The provisions of §103(c) do not apply and the '283, '049, and '837 applications are not prior art against the present application.

Thus, Applicants respectfully submit that the requirements for a proper double patenting rejection as set forth in the MPEP are not met in this case, and therefore, the present double patenting rejection is improper.

For all these reasons, the rejection of the claims on the ground of non-statutory obviousness-type double patenting over the '283, '049, and '837 applications should be withdrawn.

*Even if the rejections were proper, the Examiner should allow the earlier filed application to issue*

The above obviousness-type double patenting rejections are improper and should be withdrawn. These are *provisional* rejections because the alleged conflicting claims have not issued as part of a patent. Applicants respectfully note that the present application has an earlier effective U.S. filing date than the '283, '049, and '837 applications. At which time allowable subject has been agreed upon, and the provisional nonstatutory obviousness-type double patenting rejection is the only rejection remaining in the earlier filed of the pending applications, the Examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer. See, MPEP 804.

The Rejection of the Claims under 35 USC §112, second paragraph, Should be Withdrawn

Claims 1-7, 13, 21, and 22 were rejected under 35 USC §112, second paragraph, as being indefinite. This rejection is respectfully traversed.

The Examiner objected to the use of the term "optionally" in claim 1. Accordingly, the claims have been amended to remove this term and the rejection should be withdrawn.

Claim 4 was rejected under 35 U.S.C. §112, second paragraph, for being indefinite. The Examiner states that the recited protein was removed from the GenBank data base and thus it is unclear what protein is recited in the claim. While GenBank Accession No. XP_003891 has been removed from the database, the polypeptide sequence is still present in the database. So while it is clear what sequence is claimed, to overcome the rejection a sequence listing has been submitted with this response containing the sequence shown in GenBank Accession No. XP_003891 and claim 4 has been amended to recite the appropriate SEQ ID NO. Accordingly, the rejection over claim 4 should be withdrawn.

Claim 5 was rejected under 35 U.S.C. §112, second paragraph, for being indefinite. Specifically, the Examiner questions the meaning of "follistatin/chelate, follistatin/drug, follistatin/prodrug, follistatin/toxin, follistatin detector group, and follistatin imaging marker." 35 U.S.C. §112, second paragraph, simply requires that one of skill in the art at the time of filing would have understood the claim terms used. The terms objected to by the Examiner refer to

follistatin and the additional compound recited. One of skill in the art would understand the claim to mean such. Accordingly, the rejection should be withdrawn.

The Rejections of the Claims Under 35 U.S.C. §102 Should be Withdrawn

Claims 1, 2, 6, 7, 13, 21, and 22 were rejected under 35 U.S.C. §102(b) as being anticipated by Bartholin *et al.* (2001, Sept. 6) *Oncogene* 20:5409-19. This rejection is respectfully traversed.

The present application claims priority under 35 U.S.C. §119 to Australian Application No. PR6381, filed July 13, 2001. The claim to priority has already been made in the instant application via the filing of the priority claim in the application data sheet and a certified copy of AU application no. PR6381 was filed in the U.S. PTO on June 21, 2004. The inventors of AU application no. PR6381 are identical to the inventors of the present application. Accordingly, the Bartholin *et al.* reference is not a prior art reference with respect to the present application and the rejection should be withdrawn.

Claims 1, 2, 3, 5, 13, 21, and 22 were rejected under 35 U.S.C. §102(b) as being anticipated by US Patent No. 5,041,538 (the '538 patent). This rejection is respectfully traversed.

The '538 patent discloses the isolation of follistatin 315 and 288, and the prophetic use of these molecules for decreasing fertility/spermatogenesis in female/male mammals (column 10, lines 1-14). The patent suggests a dosage of from about 0.1 to about 1mg per kg of body weight for administration on a regular basis as a male contraceptive (column 12, lines 16-21). There is no data, either *in vivo* or *in vitro*, to support the suggested use let alone the suggested dosage rates. Furthermore, the patent provides no guidance with respect to how to formulate follistatin as a pharmaceutical composition. Accordingly, the rejection of the amended claims over the '538 patent should be withdrawn.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

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